NOV 23 2011

# ARCHITECT 25-OH Vitamin D

## 510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **k110619**

**Preparation Date**: November 16th, 2011

**Applicant Name:**
Mr. Joan Guixer
Director of Quality Assurance and Regulatory Affairs
Biokit S.A.
Lliça d'Amunt
Barcelona, Spain 08186

**Device Name:**
Reagents
Classification Name: Vitamin D test system
Trade Name: ARCHITECT 25-OH Vitamin D Immunoassay
Common Name: Vitamin D test system
Governing Regulation: 862.1825
Device Classification: Class II
Product Code: MRG

Calibrators:
Trade Name: ARCHITECT 25-OH Vitamin D Calibrators (A-F)
Common Name: Calibrator
Governing Regulation: 862.1150
Device Classification: Class II
Classification Panel: Chemistry
Product Code: JIT

Controls:
Trade Name: ARCHITECT 25-OH Vitamin D Controls (Low, Medium and High)
Common Name: Control
Governing Regulation: 862.1660
Device Classification: Class I
Classification Panel: Chemistry
Product Code: JJX

**Legally marketed device to which equivalency is claimed:**
LIAISON® 25 OH Vitamin D TOTAL (k071480)

**Intended Use of Device:**
The ARCHITECT 25-OH Vitamin D assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of 25-hydroxyvitamin D (25-OH vitamin D) in human serum and plasma. The ARCHITECT 25-OH Vitamin D assay is to be used as an aid in the assessment of vitamin D sufficiency.

The ARCHITECT 25-OH Vitamin D Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of 25-hydroxyvitamin D (25-OH Vitamin D) in human serum and plasma.

The ARCHITECT 25-OH Vitamin D Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System when used for the quantitative determination of 25-hydroxyvitamin D (25-OH Vitamin D) in human serum and plasma.

**Description of Device:**
The ARCHITECT 25-OH Vitamin D assay is a delayed one-step immunoassay including a sample pre-treatment for the quantitative determination of vitamin D in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.
Sample and pre-treatment reagent are combined. An aliquot of the pre-treated sample is combined with assay diluent and paramagnetic anti-vitamin D coated microparticles to create a reaction mixture. Vitamin D present in the sample binds to anti-vitamin D coated microparticles. After incubation a biotinylated vitamin D anti-Biotin acridinium-labeled conjugate complex is added to the reaction mixture and binds to unoccupied binding sites of the anti-vitamin D coated microparticles. After washing, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). An indirect relationship exists between the amount of vitamin D in the sample and the RLUs detected by the ARCHITECT *i* System optics.

**Comparison of Technological Characteristics:**
The ARCHITECT 25-OH Vitamin D assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of 25-hydroxyvitamin D (25-OH vitamin D) in human serum and plasma.
The LIAISON® 25 OH Vitamin D TOTAL Assay uses chemiluminescent immunoassay (CLIA) technology for the quantitative determination of the 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites in human serum, EDTA-plasma or lithium heparin plasma to be used in the assessment of vitamin D sufficiency. Assay results should be used in conjuction with other clinical or laboratory data to assist the clinician in making individual patient management decisions in an adult population.

**Summary Performance:**
The ARCHITECT 25-OH Vitamin D assay is substantially equivalent to the LIAISON® 25 OH Vitamin D TOTAL assay in terms of precision, linearity and interferences as demonstrated in non-clinical performance data in this 510(k) submission.

The ARCHITECT 25-OH Vitamin D demonstrated substantially equivalent performance to the LIAISON® 25 OH Vitamin D TOTAL with a correlation coefficient of 0.93, a slope of 0.97 and an intercept of -1.07.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 23 2011

Biokit S.A
c/o Joan Guixer
Can Male S/N
Llissa D'Amunt, Barcelona
Spain 08186

Re: k110619
Trade Name: Architect 25-OH Vitamin D Assay,
Architect 25-OH Vitamin D Calibrators,
Architect 25-OH Vitamin D Controls
Regulation Number: 21 CFR §862.1825
Regulation Name: Vitamin D Test System
Regulatory Class: Class II
Product Codes: MRG, JIT, JJX
Dated: November 18, 2011
Received: November 22, 2011

Dear Joan Guixer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

**510(k) Number (if known):** K110619

**Device Name:** ARCHITECT 25-OH Vitamin D Reagents, ARCHITECT 25-OH Vitamin D Calibrators (A-F) and ARCHITECT 25-OH Vitamin D Controls (Low, Medium and High)

**Indication for Use:**

**Reagents**

The ARCHITECT 25-OH Vitamin D assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of 25-hydroxyvitamin D (25-OH vitamin D) in human serum and plasma. The ARCHITECT 25-OH Vitamin D assay is to be used as an aid in the assessment of vitamin D sufficiency.

**Calibrators**

The ARCHITECT 25-OH Vitamin D Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of 25-hydroxyvitamin D (25-OH Vitamin D) in human serum and plasma.

**Controls**

The ARCHITECT 25-OH Vitamin D Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System when used for the quantitative determination of 25-hydroxyvitamin D (25-OH Vitamin D) in human serum and plasma.

For *in vitro* diagnostic use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) **OR** Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

**Division Sign-Off**

**Office of In Vitro Diagnostic Device Evaluation and Safety**

510(k) K110619